

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 20 – COMMUNITY HEALTH

SUBCHAPTER 15 - INFORMATION FOR HEALTH CARE PROFESSIONALS

PART 7 – Immunization, Testing, and Health Screening for Health Care Workers

7.1 Purpose

These regulations establish requirements for adopting standards for immunization and communicable disease screening and testing for health care workers prior to employment in Rhode Island-licensed health care facilities.

7.2 Authority

These regulations are promulgated pursuant to the authority conferred under Chapters 23-17 and 23-17.7.1 of the General Laws of Rhode Island.

7.3 Incorporated Materials

- A. These regulations hereby adopt and incorporate the Rhode Island Department of Health Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases (November 2013) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
<http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/7434.pdf>
- B. These regulations hereby adopt and incorporate the Centers for Disease Control and Prevention (CDC) General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR, Recommendations and Reports (January 2011) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
<https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>
- C. These regulations hereby adopt and incorporate the CDC Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (November 2011) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
<https://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf>
- D. These regulations hereby adopt and incorporate the CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care

Settings MMWR, Recommendations and Reports (December 2005) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm>

- E. These regulations hereby adopt and incorporate the Occupational Safety and Health Administration (OSHA) Blood Borne Pathogens Standard (29CFR 1910-1030), (APRIL 2001) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_tab=STANDARDS

7.4 Definitions

- A. Wherever used in these Regulations, the following terms shall be construed as follows:
1. "Advisory Committee on Immunization Practices (ACIP) recommendations", as used in these Regulations, means official federal recommendations for the use of vaccines in the United States and as published by the Centers for Disease Control and Prevention. ACIP recommendations represent the standard of care for immunization practice in the United States.
 2. "Certified registered nurse practitioner (RNP)" means a registered nurse who practices in an advanced role utilizing independent knowledge of physical assessment and management of health care and illnesses. The practice includes prescriptive privileges, and collaboration with other licensed health care professionals, including, but not limited to, physicians, pharmacists, podiatrists, dentists and nurses.
 3. "Department" means the Rhode Island Department of Health.
 4. "Direct patient contact", as used in these Regulations, means any routinely anticipated face-to-face interaction with patients in a health care facility.
 5. "Director" means the Director of the Rhode Island Department of Health.
 6. "Health care worker" means any person who is temporarily or permanently employed by or at, or who serves as a volunteer in, or has an employment contract with, a health care facility, as defined in §7.5(A)(1) of this Part, and has or may have direct contact with a patient in that health care facility. This may include, but not be limited to, a physician, physician assistant, nurse, nursing assistant, therapist, technician, clinician, behavioral analyst, social worker, occupational, physical or speech

therapist, phlebotomist, emergency medical service personnel, dental personnel, pharmacist, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility; other health care providers, including those have privileges at, but are not employed by, the health care facility; and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from a health care worker and a patient. This term shall not apply to a patient's family member or friend who visits or otherwise assists in the care of that patient in a health care facility.

7. "Nurse" means an individual licensed in this state to practice nursing pursuant to the provisions of R.I. Gen. Laws Chapter 5-34.
8. "Physician", as used in these Regulations, means an individual licensed under the provisions of R.I. Gen. Laws Chapter 5-37 or an individual licensed to practice allopathic or osteopathic medicine under the laws of another state or territory of the United States, provided those laws are deemed to be substantially equivalent to R.I. Gen. Laws Chapter 5-37.
9. "Physician assistant" means an individual licensed in this state to practice with physician supervision pursuant to the provisions of R.I. Gen. Laws Chapter 5-54.
10. "Practitioner", as used in these Regulations, means a physician, certified registered nurse practitioner, registered nurse, licensed practical nurse, or a physician assistant.
11. "Pre-employment health screening" means the review of health records, pertinent laboratory results, and other documentation of a health care worker performed by a licensed practitioner in order to determine that the health care worker is free of the communicable diseases cited in these Regulations, and is also appropriately immunized, tested, and counseled prior to employment.
12. "These Regulations" mean all parts of Rhode Island Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers [216-RICR-20-15-7].

7.5 General Requirements

- A. Health care facilities shall adopt, at a minimum, the standards of immunization and communicable disease testing and standards for health screening contained in §7.6 of this Part of these Regulations. For these Regulations:

1. "Health care facility" means any institutional health service provider, facility or institution, place, building, agency, or portion thereof, whether a partnership or corporation, whether public or private, whether organized for profit or not, used, operated, or engaged in providing health care services, including but not limited to hospitals; nursing facilities; home nursing care provider (which shall include skilled nursing services and may also include activities allowed as a home care provider, or as a nursing service agency); home care provider (which may include services such as personal care or homemaker services or as a nursing service agency); rehabilitation centers; kidney disease treatment centers; health maintenance organizations; free- standing emergency care facilities, and facilities providing surgical treatment to patients not requiring hospitalization (surgi-centers); hospice care, physician ambulatory surgical centers and podiatry ambulatory surgery centers providing surgical treatment and nursing service agencies licensed under the provisions of R.I. Gen. Laws §23-17.7.1.
2. Except as provided in §7.5(A)(3) of these Regulations, health care facility also includes organized ambulatory care facilities which are not part of a hospital but which are organized and operated to provide health care services to outpatients such as central services facilities serving more than one health care facility or health care provider, treatment centers, diagnostic centers, outpatient clinics, infirmaries and health centers, school-based health centers and neighborhood health centers.
3. The term "health care facility" shall not apply to organized ambulatory care facilities owned and operated by professional service corporations as defined in R.I. Gen. Laws Chapter 7- 5.1, as amended (the "Professional Service Corporation Law"), or to a private practitioner's (physician, dentist, or other health care provider) office or group of the practitioners' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, organization, or association).
4. Any provider of hospice care who provides such hospice care without charge shall be exempt from the licensing provisions of R.I. Gen. Laws Chapter 23-17, but shall meet the "Standards of a Hospice Program of Care."
5. Facilities licensed by the Department of Behavioral Healthcare, Developmental Disabilities and Hospitals and clinical laboratories licensed in accordance with R.I. Gen. Laws §23-16.2, as well as Christian Science institutions (also known as Christian Science Nursing Facilities) listed and certified by the Commission for Accreditation of Christian Science Nursing Organizations/Facilities, Inc. shall not be considered health care facilities for purposes of R.I. Gen. Laws Chapter 23-17.

- B. It shall be the responsibility of the administrative head, or his/her designee, of any health care facility to secure compliance with these Regulations.
- C. Each health care facility shall develop policies, procedures, and/or protocols for compliance with the requirements described in these Regulations.
- D. Transient employees or outside contractors who are not involved in direct patient contact are exempt from the requirements stated in these Regulations.
- E. Health care facilities and health care workers shall comply with additional immunization and screening requirements that the Director may prescribe from time to time to control communicable diseases.
- F. Persons discovering communicable diseases (e.g., physicians, physician assistants, registered nurse practitioners), in the process of screening health care workers shall comply with the reporting requirements contained in §7.3(A) of this Part of these Regulations .
- G. In accordance with ACIP recommendations, for all vaccines discussed in these Regulations, vaccine doses administered less than or equal to four (4) days before the minimum interval or age shall be counted as valid. Doses administered five (5) or more days earlier than the minimum interval or age shall not be counted as valid doses and shall be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval as provided in §7.3(B) of this Part of these Regulations.
- H. Health care workers who receive the first dose of a multi-dose vaccine series may begin to work after this first dose is received.

7.6 Minimum Standards for Immunization and Communicable Disease Testing for Health Care Workers

- A. A pre-employment health screening shall be required for each health care worker involved in direct patient contact. Acceptable evidence shall be provided by the health care worker that testing and/or immunization for the communicable diseases listed in these Regulations for pre-employment health screening have been completed.
- B. The health care facility shall document, in written or electronic form, that said acceptable evidence has been provided by the health care worker and validated by the practitioner as being acceptable in accordance with §7.7 of these Regulations. Copies of said acceptable evidence shall be maintained in the health care worker's file.
- C. A practitioner shall have responsibility for performance of the pre-employment health screening. Such a practitioner may be an employee of the facility where

employment is sought or may be an independent non-employee, contracted practitioner.

- D. A health care worker who is not in compliance with these requirements shall be excluded from attending patients in a health care facility until the requirements are met.

7.6.1 Immunization and Testing Requirements

- A. In accordance with the guidelines set forth in §7.3(C) of this Part of these Regulations, evidence of immunity is required for all health care workers (except for health care workers who receive a medical exemption) against:

- 1. Measles, Mumps and Rubella:

- a. Pre Employment: Two (2) doses of MMR (measles-mumps-rubella) vaccine. Alternatively, two (2) doses of a live measles-containing vaccine, two (2) doses of a live mumps-containing vaccine and one (1) dose of a rubella vaccine. The first dose of vaccine must have been administered on or after the first birthday. The second dose of a measles or mumps containing vaccine must be administered at least four (4) weeks after the first dose. OR
- b. Laboratory evidence of immunity or laboratory confirmation of disease (i.e., laboratory report of positive IgG titers for measles, and mumps and rubella). An equivocal laboratory result for measles, mumps and/or rubella are considered negative and vaccination is required.
- c. Current Health Care Workers. For unvaccinated health care workers born before 1957 who lack laboratory evidence of measles immunity or laboratory confirmation of disease, two (2) doses of MMR vaccine is recommended.
- d. Outbreak Control. For unvaccinated health care workers born before 1957 who lack laboratory evidence of measles immunity or laboratory confirmation of disease, health-care facilities shall require two (2) doses of MMR vaccine during an outbreak of measles.

- 2. Varicella (Chickenpox):

- a. Two (2) doses of varicella vaccine. The second dose of varicella vaccine must be administered at least four (4) weeks after the first dose; OR
- b. Laboratory evidence of immunity or laboratory confirmation of disease; OR

- c. A healthcare provider diagnosis of varicella or healthcare provider verification of history of varicella disease; OR
 - d. History of herpes zoster based on healthcare provider diagnosis.
- 3. Tetanus, Diphtheria and Pertussis (Whooping Cough):
 - a. Pre-employment: One (1) single dose of Tdap (tetanus-diphtheria-pertussis) vaccine is required for all health care workers who have not previously received a dose of Tdap vaccine.
 - b. Effective 1 January 2014: This requirement shall apply to current employees, as well as new employees.
- 4. Annual Seasonal Influenza:
 - a. Annual influenza vaccination is required for all health care workers as defined in §7.4, subject to 7.8(H) when there is insufficient vaccine supply as determined by the Department.
 - b. Each health care facility shall develop a specific plan to require annual influenza vaccination of all health care workers in a timely manner in keeping with ACIP guidelines, and at no cost to the health care worker.
 - c. Each health care facility shall maintain an active surveillance program to track and record influenza vaccination levels among health care workers, including vaccinations obtained outside of the formal health care facility program.
 - d. Each health care facility shall be responsible for reporting to the Department:
 - (1) The number of health care workers who are eligible for vaccination;
 - (2) The number of health care workers who received vaccination; and
 - (3) The number of health care workers who decline annual influenza vaccination for medical or personal reasons, reported by each of the two (2) categories.
 - (4) Such reporting shall occur according to procedures and format required by the Department.
- 5. Tuberculosis (TB):

- a. Pre-employment: Evidence that the health care worker is free of active tuberculosis based upon the results of a negative two-step tuberculin skin test shall be required.

- (1) If documented evidence is provided by the health care worker that a two- step tuberculin skin test, performed within the most recent twelve (12) months prior to hire, was negative, the requirements of this section shall be met.

For health care workers who can present documentation of serial tuberculin testing with negative results in the prior two (2) years (or more), a single baseline negative tuberculin test result is sufficient evidence of absence of TB infection.

- (2) A negative FDA-approved blood assay for Mycobacterium tuberculosis (BAMT) may be used instead of a two-step tuberculin skin test. If the baseline BAMT is positive, screening should proceed as indicated below for positive PPD.
- (3) Documentation shall include date and result of the tuberculin skin test (PPD), and reaction size in millimeters or an actual copy of the laboratory test result from a BAMT.
- (4) If the PPD test or BAMT is positive, consistent with the most current Centers for Disease Control and Prevention{CDC} guidance, or a previous one is known to have been positive, a physician's or other licensed practitioner's (acting within his/her scope of practice) certification that the health care worker is free of active disease shall be required. Such certification shall be based on documentation of adequate chemotherapy for TB disease or chemo-prophylaxis for latent TB infection in the past, and a current history of freedom from signs and symptoms of TB. In the absence of documentation of chemotherapy or chemo-prophylaxis, a negative chest X-ray shall be required for certification. The chest x-ray shall have been performed at any time after the most recent positive PPD test result.
- (5) A physician, certified registered nurse practitioner, or a physician assistant may certify that the health care worker is currently free of TB based on his/her clinical judgment for complex cases or unusual circumstances that do not fit the above criteria.

- b. Current Health Care Workers:

- (1) Periodic follow up testing of all health care workers must be based on the CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings incorporated above at §7.3(D) of this Part.
- (2) Effective 1 January 2013, health care workers with newly detected latent TB infection (LTBI) at initial or periodic testing are required to be referred for care with intent to obtain treatment for latent TB infection. Referral of previously (prior to 1 January 2013) known LTBI for care is recommended.
- (3) Effective 1 January 2013, LTBI cases detected in health care workers must also be reported to the RI TB Program on standard reporting forms.

6. Hepatitis B Vaccination and Testing:

- a. Health care facilities shall abide by the OSHA Blood Borne Pathogens Standard, incorporated above at §7.3(E) of this Part including the offering of hepatitis B vaccination along with all recommendations for infection control training and provision of protective equipment to those health care workers at risk.
- b. An exposure control plan shall be in place in all health care facilities licensed by the Department, pursuant to the provisions of R.I. Gen. Laws Chapter 23-17.
- c. Employees at risk of exposure to blood-borne pathogens shall be offered hepatitis B vaccine within ten (10) days of employment.
 - (1) The hepatitis B vaccination series consists of three (3) doses of vaccine given as two (2) doses four (4) weeks apart followed by a third dose five (5) months after the second dose.
 - (2) It is recommended that testing for anti-HBs be performed one (1) to two (2) months after the last dose.
 - (3) Persons failing to develop a titer shall be offered a repeat three (3) dose series with follow up titers.
 - (4) Employees have the option of signing a standard OSHA declination form if they choose not to be vaccinated and should be counseled regarding risk.
- d. If the health care worker, upon hire, has written documentation of a full hepatitis B vaccine series administered in accordance with

ACIP guidelines, testing for anti-HBs shall not be necessary. If the health care worker has a subsequent exposure to HBV, hepatitis B immunoprophylaxis should be administered following ACIP guidelines for a person who has been vaccinated, but the immune response is not known.

7.7 Documentation of Immunity and Testing (Immunization Records)

- A. Acceptable documentation of completion of immunizations shall include the day, month, year and type/name of each dose of vaccine administered. The record of such evidence shall be signed by a practitioner (the signature of the health care worker is not acceptable).
 - 1. Acceptable documentation of completion of immunization consists of:
 - a. An official immunization record card, school immunization record, medical passport, World Health Organization immunization record, a copy of a medical record indicating administration of vaccine; or other official immunization records acceptable to the Director; OR
 - b. An electronically stored and/or transmitted documentary record (facsimile transmission, computerized record, including, but not limited to, a record on magnetic media or similar record) as may be utilized by a school; OR
 - c. Presentation of laboratory evidence of immunity is made in the case of measles, mumps, rubella, varicella, or hepatitis B.

7.8 Medical Exemption and Influenza Vaccination Refusal

- A. A health care worker shall be exempt from the immunization requirements described in these Regulations provided that a physician, physician assistant, or certified registered nurse practitioner signs a medical exemption stating that the health care worker is exempt from a specific vaccine because of medical reasons, in accordance with Advisory Committee on Immunization Practices (ACIP) guidelines incorporated above at §7.3(B) of this Part, and determined as acceptable by the facility.
- B. A "period in which flu is widespread" is defined for purposes of these Regulations as a period that commences when the Director declares that there is an outbreak of influenza that is widespread within a facility, or within a defined geographic area in which the facility is located, or throughout Rhode Island; and that ends when the Director declares to such a health care facility or facilities that the outbreak is no longer widespread. Whenever the Director declares a "period in which flu is widespread" in a health care facility, within a defined geographic area, or throughout Rhode Island, the requirements in §7.8 of this Part of these Regulations for wearing surgical face masks shall apply only to those

nonimmunized health care workers at facilities or in geographic areas for which the period is declared.

- C. Any health care worker who provides proper annual notice of a medical exemption to annual seasonal influenza vaccination prior to December 15 of each year to each health care facility in or at which he or she is employed or volunteering, or with which he or she has an employment contract, shall be required during any declared period in which flu is widespread -- as part of his or her professional licensing obligation -- to wear a surgical face mask for the duration of each direct patient contact in the performance of his or her duties at any health care facility. "Direct patient contact" is defined in §7.4 of this Part of these Regulations.
- D. Any health care worker may refuse the annual seasonal influenza vaccination requirements described in these Regulations; provided, however, that he or she provides proper annual written notice of such refusal prior to December 15 of each year to each health care facility in or at which he or she is employed or volunteering, or with which he or she has an employment contract; and provided, however, that he or she who so refuses shall be required during any declared period in which flu is widespread -- as part of his or her professional licensing obligation -- to wear a surgical face mask during each direct patient contact in the performance of his or her duties at any health care facility. "Direct patient contact" is defined in §7.4 of this Part of these Regulations
- E. Each such yearly notice required by §7.8(D) of this Part of these Regulations shall contain the following statement: "I refuse to obtain the annual seasonal influenza vaccination. I understand that, by refusing such vaccination, it is my professional licensing obligation to wear a surgical face mask during each direct patient contact in the performance of my professional duties at any health care facility during any declared period in which flu is widespread. I understand that the consequence for failing to do so shall result in a one hundred dollar (\$100) fine for each violation. Failing to do so may also result in a complaint of Unprofessional Conduct being presented to the licensing board that has authority over my professional license. I understand that such licensing complaint, if proven, may result in a sanction such as reprimand, or suspension or revocation of my professional license." Such statement shall be signed and dated by the health care worker each year that it is submitted to each health care facility at or in which the health care worker is employed, or with which he or she has an employment contract. No health care worker shall be required to explain his or her refusal to obtain an annual seasonal influenza vaccination, nor shall any health care facility inquire into the basis of such refusal.
- F. Any health care worker who holds a license issued by the Department and who shall violate §7.8(C), §7.8(D) or §7.8(E) of these Regulations shall be subject, pursuant to R.I. Gen. Law § 23-1- 25, to a fine of one hundred dollars (\$100) for each such act. Each such act shall be considered to meet the definition of

“unprofessional conduct” as used in each chapter of the Rhode Island General Laws that governs each health care worker’s respective professional license.

- G. Each act that violates §7.8(C), §7.8(D) or §7.8(E) of this Part of these Regulations shall form a separate basis for each complaint that may be brought for disciplinary action, based on unprofessional conduct, before the licensing board that has authority over the health care worker’s license issued by the Department. The requirements of §7.8(C), §7.8(D) and §7.8(E) of this Part of these Regulations apply to each health care worker regardless of any provision in any collective bargaining agreement or other contract to which the health care facility and health care workers are parties, or of any written policy of the health care facility.
- H. If the Director declares that a shortage exists for annual seasonal influenza vaccine, the Director shall be permitted to modify and/or suspend any requirement for some or all health care workers to obtain an annual seasonal influenza vaccination and/or any requirement for health care workers to wear surgical face masks during any direct patient contact in the performance of his or her professional duties in any health care facility; and shall be permitted to extend the deadlines in §7.8(C) and §7.8(D) of this Part of these Regulations.
- I. Any health care facility that knowingly, willingly and expressly refuses to require its health care workers who have refused an annual seasonal influenza vaccination, or who have a §7.8(A) medical exemption, to wear a surgical face mask during each direct patient contact in the performance of his or her professional duties in any health care facility during any declared period in which flu is widespread shall be subject, pursuant to R.I. Gen. Laws§ 23-1-25, to a fine of one hundred dollars (\$100) for each such violation committed by any health care worker who is employed or volunteering in, or has an employment contract with, such facility. No health care facility shall be fined for the act of any health care worker who falsely informs such facility about his or her medical exemption and/or refusal pursuant to §7.8(A) or §7.8(D) of this Part of these Regulations.
- J. Each health care facility shall provide at no financial charge an adequate supply of surgical face masks -- during any declared period in which flu is widespread at the facility, in the geographic area in which it located, or statewide -- to any health care worker who has claimed a medical exemption to or has refused the annual seasonal influenza vaccination.
- K. The purpose of these Regulations relating to annual seasonal influenza vaccination for health care workers is to protect the public as a whole, patients at health care facilities, and in particular those vulnerable to contracting annual seasonal influenza due to compromised immunity and other medical conditions. Health care workers each have a potential for spreading the disease of influenza to their patients, and it is the right of patients in health care facilities to be as safe as possible from the spread of this and other infectious diseases. The reasonable precaution of having each health care worker receive annual seasonal influenza

vaccination is expected to significantly reduce the incidence of seasonal influenza in health care facilities. The purpose of allowing health care workers to wear surgical masks during direct patient contact during any declared period in which flu is widespread -- in the event they refuse, or have a medical exemption to, an annual seasonal influenza vaccination -- is to ensure patient safety and to reduce the chance of health care workers spreading the influenza virus. Scientific research has shown that the wearing of surgical face masks reduces the transmission of the influenza virus to other human beings. It is not the intent of these regulations to impose an unnecessary burden on health care workers but to effectively protect the public.

7.9 Severability

If any provision of these Regulations or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.